(ii) at least one heterologous gene; and

a second DNA sequence [encoding a DNA sequence capable of] encoding packaging components env and *gag-pol* wherein the DNA sequence encoding env is present on a separate construct [to] than the DNA sequence encoding *gag-pol* [into a cell within a subject causing conversion into the cell into a producer cell].

61. (AMENDED) A method or cell according to claim 1, wherein [the components essential for retroviral function are] said defective retroviral genome comprises any one or more of a primer binding site, integration sites and a packaging signal.

63. (NEW) The producer cell of claim 51, wherein said producer cell is a fresh cell from a subject.

REMARKS

Claims 47-56, 58-61 and 63 are currently pending.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 22-25, 31-34 and 42-45 were rejected under 35 U.S.C. § 112, first paragraph, as not enabled. Claims 22-25, 31-34 and 42-45 were canceled without prejudice by the Amendment submitted September 27, 2000. Claims 57 and 62, added by the Amendment filed September 27, 2000, have now been canceled. Applicants respectfully traverse this rejection as it may be applied to any of the pending claims.

Applicants respectfully submit that the application provides sufficient exemplification to make and use the invention as claimed.

Independent claim 47 recites a method for introducing a heterologous gene into a target cell comprising introducing a first and second DNA sequence into a cell of a subject. Independent claim 51 recites a producer cell which comprises a first and second DNA sequence. Independent claim 59 recites a method for making a producer cell comprising introducing a first and second DNA sequence into a cell.

One of skill in the art is familiar with a variety of methods for introducing many different heterologous genes into different cell types. Additionally, the disclosure for the present invention describes a number of delivery methods. Applicants are not required to provide examples of all possible delivery methods, heterologous genes or cell types.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosure of the patent coupled with information known in the art without undue experimentation. A patent may be enabling even though some experimentation is necessary, so long as the amount of experimentation is not "undue". See *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); and *United States v. Telectronics, Inc.* 857 F.2d 778 (Fed. Cir. 1988).

Because one of skill in the art could readily devise a suitable method for introducing a DNA sequence encoding a defective retroviral genome and a DNA sequence encoding packaging components *env* and *gag-pol* into a cell, Applicants respectfully request withdrawal of this rejection.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 22, 25, 31, 33-34 and 41-46 were rejected under 35 U.S.C. § 112, second paragraph as indefinite. Claims 22, 25, 31, 33-34 and 41-46 were canceled without prejudice by the Amendment submitted September 27, 2000. Claims 57 and 62, added by the Amendment filed September 27, 2000, have now been canceled. Applicants respectfully traverse this rejection as it may be applied to any of the pending claims.

The phrase "essential for retroviral functions" has been deleted from the pending claims. Additionally, the amended claims do not recite the phrase "expressing within a producer cell" or "capable of." Therefore these rejections are moot. Applicants respectfully request withdrawal of these rejections.

CONCLUSION

In view of the amendments and remarks presented herein, it is respectfully submitted that the application is in condition for allowance and notification to that effect is earnestly solicited. The Examiner is encouraged to contact Applicant's undersigned attorney to discuss this application if any questions should arise upon further examination of the pending claims.

Respectfully submitted,

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